

Exhibit 1

Proposed Consent Decree

Exhibit 1

**UNITED STATES DISTRICT COURT
DISTRICT OF NEVADA**

* * * *

IN RE: HCV PRISON LITIGATION

Case No: 3:19-cv-00577-MMD-CLB

PROPOSED CONSENT DECREE

I. INTRODUCTION

A. The Parties:

10 1. Plaintiffs: Class Representatives Marty Scott Fitzgerald, Elizabeth Carley, Donald Savage,
11 Howard White, Carl Olsen, Scott Bedard, Stephen Ciolino and Mitchell Fields (“Class
12 Representatives”) who filed a Class Action Complaint (“Complaint”) on December 9, 2019
13 (ECF No. 10) individually and on behalf of a class of similarly situated persons (“Class
14 Members”), by and through their undersigned counsel (“Class Counsel”).

15 2. Defendants: The STATE OF NEVADA *ex rel.* NEVADA DEPARTMENT OF
16 CORRECTIONS (“NDOC”), on behalf of itself and all of its officers, directors, employees,
17 former employees, agents, predecessors, divisions, correctional facilities, successors,
18 administrators, and assigns, including, but not limited to Director Charles Daniels, former
19 Acting Director and current Deputy Director of Operations Harold Wickham, former
20 Director James Dzurenda, former Medical Director Romeo Aranas, M.D., current Medical
21 Director, Michael Minev, M.D., and any other persons named (or could have been named)
22 in the Complaint who are or were NDOC or State of Nevada employees (collectively
23 referred to as “the NDOC” or “Defendants”).

24 3. Plaintiffs and Defendants are collectively referred to herein as the “Parties” or individually
25 as a “Party.”

26 **B. DISPUTES/LITIGATION**

27 4. This action relates to the testing and treatment of inmates with the chronic Hepatitis C
28 Virus (“HCV”) who are or will be in NDOC custody.

1 5. On October 9, 2019, this Court issued Pre-Trial Order #1: Initial Case Conference (ECF
 2 No. 1). Through that Order, the Court consolidated fourteen (14) cases, which presented
 3 similar issues related to HCV:

4 • 2:17-CV-1627-MMD-CBC Reese v. Foxfulker, et. al.
 5 • 2:17-CV-1725-MMD-CBC Fields v. Neven, et. al.
 6 • 2:17-CV-2346-MMD-CBC Carley v. Neven, et. al.
 7 • 2:19-CV-0213-MMD-CBC Flynn v. Dzurenda, et. al.
 8 • 2:19-CV-0520-MMD-CBC Ciolino v. Dzurenda, et. al.
 9 • 3:16-CV-0676-MMD-CBC Nevarez v. Baca, et. al.
 10 • 3:17-CV-0278-MMD-CBC Fitzgerald v. Martin, et. al.
 11 • 3:17-CV-0612-MMD-CBC Savage v. Aranas, et. al.
 12 • 3:18-CV-0037-MMD-CBC White v. Aranas, et. al.
 13 • 3:18-CV-0149-MMD-CBC Olsen v. Nevada Department of Corrections, et. al.
 14 • 3:18-CV-0218-MMD-CBC Bedard v. Nevada Department of Corrections, et. al.
 15 • 3:18-CV-0386-MMD-CBC Mulder v. Marks, et. al.
 16 • 3:18-CV-0464-MMD-CBC Thomas v. Dzurenda, et. al.
 17 • 3:19-CV-0300-MMD-CBC Klein v. Williams, et. al.

18 6. On December 9, 2019, Class Counsel filed an Amended Class Action Complaint
 19 ("Complaint") and Motion to Certify Class. (ECF Nos. 10, 11). The Complaint was filed
 20 on behalf of eight named plaintiffs, the Class Representatives, whose individual cases were
 21 stayed during the pendency of the class action proceedings. The other consolidated cases
 22 were also stayed, even for those plaintiffs who did not serve as Class Representatives.

23 7. Defendants answered the Complaint on January 21, 2020 and filed a Response to Motion
 24 to Certify Class on the same day. (ECF Nos. 18, 19).

25 8. On February 18, 2020, the Court granted the Motion to Certify Class. (ECF No. 21). Adam
 26 Hosmer-Henner, Margaret A. McLetchie, and their chosen litigation teams were appointed
 27 as Class Counsel. *Id.* The Court certified a class of "all persons: (a) who are or will be in
 28 the legal custody of NDOC; (b) who have been incarcerated for at least 21 days and have
 1 at least 12 weeks remaining on their sentence; (c) who have been diagnosed with chronic
 2 HCV and are candidates for DAA treatment pursuant to the proper medical standard of
 3 care; and (d) for whom DAA treatment has been or will be denied, withheld, or delayed
 4 based on policies or considerations that deviate from the proper medical standard of care."

5 *Id.*

6 //

1 9. The Court further ordered that the following issues were certified for class litigation: “(1)
2 whether HCV is a serious medical need; (2) whether NDOC’s policy and practice of not
3 providing HCV treatment constitutes deliberate indifference to serious medical needs in
4 violation of the Eight Amendment; (3) whether NDOC has knowingly failed to provide the
5 necessary staging of HCV patients in accordance with the prevailing medical standard of
6 care, including the pretreatment testing to determine the severity of the disease; (4) whether
7 NDOC has knowingly employed policies and practices that unjustifiably delay or deny
8 treatment for HCV; (5) whether NDOC has permitted cost considerations to improperly
9 interfere with the treatment of HCV; (6) whether HCV is a disability under the ADA
10 (Americans with Disabilities Act); (7) whether medical services in prison are a program or
11 service under the ADA; and (8) whether Defendant has discriminated against NDOC
12 inmates with HCV on the basis of their disability by categorically denying them medical
13 treatment, while providing treatment for other diseases and conditions.” (ECF No. 21).

14 10. The Parties submitted a Proposed Stipulated Discovery Plan and Scheduling Order on April
15 2, 2020 (ECF No. 32) and the Court entered a Scheduling Order on April 3, 2020 (ECF
16 No. 34).

17 11. The Parties engaged in written discovery throughout the first phase of the discovery plan.
18 Although the Parties did not disclose expert reports prior to settlement, both sides also
19 engaged experts and consulted with them extensively.

20 12. The Parties participated in a telephonic pre-settlement conference on June 24, 2020 with
21 Magistrate Judge Cobb and the entered into a stipulation to stay further discovery and
22 discovery deadlines pending the outcome of settlement discussions. (ECF Nos. 45, 46).

23 13. The Parties participated in a settlement conference with Magistrate Judge Cobb on July 9,
24 2020 and July 10, 2020. (ECF Nos. 54, 55). Thereafter, the Parties continued settlement
25 discussions on August 6, 2020 (ECF No. 59) with Magistrate Judge Cobb, in addition to
26 additional numerous hours spent on videoconferences and teleconferences in between and
27 after the formal settlement conferences.

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C. Proposed Resolution

2 14. This Parties recognize the need to test inmates in NDOC custody for HCV and the need to
3 provide DAA treatment for HCV. At an April 14, 2020 meeting of the State of Nevada
4 Board of Examiners, Governor Sisolak remarked: “Treating [HCV inmates] in prison is
5 critical for two reasons. First, if left untreated, this disease can spread widely through the
6 prisons. Second, if not treated in prison, treatment will most likely occur after the inmate
7 has been released. A large percentage of inmates are on Medicaid and treatment later in the
8 disease lifecycle is more costly than treatment in the early stages. As a result, treatment in
9 prison is less costly to the State.”

10 15. Defendants agree that the Consent Decree meets the requirements of 18 U.S.C. §
11 3626(a)(1)(A) & (c)(1) and they will not seek to terminate or otherwise challenge the
12 Consent Decree based on a contention that it is inconsistent with the Prison Litigation
13 Reform Act. In reviewing the claims raised in the Complaint, the State of Nevada, NDOC,
14 and all individually-named Defendants deny that the NDOC and its employees engaged in
15 any culpable conduct. The NDOC's legal position was at all times, and remains, that the
16 HCV Inmate Patients' rights were not violated as all versions of (previous and current)
17 Medical Directive (MD) 219 promulgated by NDOC do not violate the Eighth Amendment
18 and that the HCV Treatment provided to HCV Inmates was and is medically appropriate
19 and in conformity with all state and federal laws, including the ADA.

20 16. By agreeing to entry of this Consent Decree, the Parties make no admission of law or fact
21 with respect to the allegations in the Complaint. For the purposes of avoiding litigation
22 among the Parties, however, the Parties agree to the requirements of this Consent Decree.

23 17. The Parties recognize, and the Court by entering this Consent Decree finds, that this
24 Consent Decree has been negotiated at arms-length by the Parties in good faith and will
25 avoid litigation among the Parties, and that this Consent Decree is fair, reasonable, and in
26 the public interest.

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1 NOW THEREFORE, it is hereby ADJUDGED, ORDERED, AND DECREED as follows:

2 **II. DEFINITIONS**

3 18. “HCV” refers to chronic Hepatitis C.

4 19. “DAA” refers to direct-acting antiviral medications.

5 20. “MD 219” refers to the medical directive adopted by Defendants related to the testing and
6 treatment of HCV by NDOC. MD 219 has been revised several times from the first version
7 relevant to this litigation, which was adopted on May 17, 2017. MD 219 was then revised
8 again in November 2019 and January 2020.

9 21. “HCV Consent Agreement” refers to the agreement signed by an inmate pursuant to MD
10 219.

11 22. “Effective Date” refers to the date on which the Court grants final approval to the Consent
12 Decree after the Parties, the State of Nevada Board of Examiners (if necessary), the State
13 of Nevada Interim Finance Committee (“IFC”) and/or the State of Nevada Legislature,
14 have all agreed to the Consent Decree. Should this Consent Decree be agreed to by the
15 Parties, the Court and IFC or Legislature on different dates, the Effective Date shall be the
16 date in which the last necessary entity (IFC, Legislature, Court) has agreed to the terms of
17 the Consent Decree.

18 23. “Class Members” or “HCV Inmate Patients” refers to all current or future inmates within
19 NDOC custody who were identified by the Court as inmates

20 (a) who are or will be in the legal custody of NDOC; (b) who have
21 been incarcerated for at least 21 days and have at least 12 weeks
22 remaining on their sentence; (c) who have been diagnosed with
23 chronic HCV and are candidates for DAA [Direct Acting Antiviral]
treatment pursuant to the proper medical standard of care; and (d)
for whom DAA treatment has been or will be denied, withheld, or
delayed based on policies or considerations that deviate from the
proper medical standard of care.^[1]

24 As the determination of which inmates would fall under categories (c) and (d) has not been
25 litigated and decided, and the Parties continue to dispute what “the proper medical standard
26 of care” is for treating incarcerated individuals with HCV, for purposes of this Consent

28 ¹ See Order, *In re: HCV Litigation*, ECF No. 21.

1 Decree, the Parties agree that all individuals incarcerated within an NDOC facility now or
2 in the future who meet the description of the class definition set forth in ¶ 25 (a)-(c) shall
3 be considered an HCV Inmate Patient making them eligible for DAA treatment, if
4 medically indicated, without regard to whether DAA Treatment for each and every HCV
5 positive inmate is constitutionally required.

6 **III. JURISDICTION AND VENUE**

7 24. This Court has jurisdiction over the subject matter of this action and over the Parties
8 pursuant to 28 U.S.C. § 1331 and 28 U.S.C. § 1343(a)(3). Venue is proper under 28 U.S.C.
9 § 1391(b)(1) and (2), because the events that gave rise to this cause of action—the
10 formulation and execution of the versions of MD 219—occurred in Nevada and the
11 Defendants reside in Nevada. For purposes of this Consent Decree and any action to
12 enforce this Consent Decree, Defendants consent to the Court’s jurisdiction over this
13 Consent Decree and any such enforcement action and consents to venue in this judicial
14 district.

15 **IV. CLASS DEFINITION**

16 25. The Court certified a class of all current or future inmates within NDOC custody who (a)
17 who are or will be in the legal custody of NDOC; (b) who have been incarcerated for at
18 least 21 days and have at least 12 weeks remaining on their sentence; (c) who have been
19 diagnosed with chronic HCV and are candidates for DAA [Direct Acting Antiviral]
20 treatment pursuant to the proper medical standard of care; and (d) for whom DAA
21 treatment has been or will be denied, withheld, or delayed based on policies or
22 considerations that deviate from the proper medical standard of care. (ECF No. 21)

23 26. For the purposes of this Consent Decree, the Parties agree that all individuals with HCV
24 incarcerated within an NDOC facility now or in the future shall be considered a member
25 of the class making them eligible for DAA treatment, if medically indicated.

26 **V. APPLICABILITY**

27 27. The obligations of this Consent Decree apply to and are binding upon the Parties, including
28 any successor agencies or other entities or persons otherwise bound by law.

1 28. Within ten (10) days of the Effective Date, Defendants shall provide a copy of this Consent
2 Decree to all officers, employees, physicians, and agents whose duties might reasonably
3 include compliance with any provision of this Consent Decree. Defendants shall also
4 provide a copy of this Consent Decree to any third parties retained by Defendants to
5 implement this Consent Decree. In any action to enforce this Consent Decree, Defendants
6 shall not raise as a defense the failure by any of its officers, directors, employees, agents,
7 or physicians to take any actions necessary to comply with the provisions of this Consent
8 Decree.

9 **VI. SUBSTANTIVE PROVISIONS**

10 **A. HCV Policies and Procedures**

11 29. Defendants agree to adopt and follow the revised version of MD 219, attached and
12 incorporated as Appendix A, and the revised version of the HCV Consent Agreement,
13 attached and incorporated as Appendix B.
14 30. Defendants agree not to use any nonmedical reason to deny class members DAA
15 Treatment, or delay DAA Treatment except as specified in Appendix A or Appendix B.
16 31. Defendants will not modify or replace MD 219 or the HCV Consent Agreement during the
17 time frame in which this Consent Decree is in force, without approval of the Court.

18 **B. Testing**

19 32. Defendants agree to test all inmates in the custody of NDOC for HCV by December 31,
20 2020.
21 33. Defendants will continue to test all inmates for HCV during the intake process, unless an
22 inmate refuses or choose to opt-out of the testing.
23 34. By January 11, 2021, Defendants will screen and prioritize all Class Members using the
24 criteria in the revised version of MD 219, attached as Appendix A.

25 **C. Treatment**

26 35. Defendants represent and warrant that, to the best of their current knowledge, as of the
27 Effective Date there are fewer than 2,400 inmates in NDOC custody who have chronic
28 HCV.

1 36. Within six (6) months from the approval of this Consent Decree by the IFC or Legislature,
2 Defendants will provide DAA Treatment to all inmates who are prioritized as Priority One,
3 as that term is further defined and described in MD 219, so long as there is no medical
4 contraindication as set forth in MD 219. Appendix A.

5 37. Within three (3) years from the Effective Date, Defendants will provide DAA treatment to
6 a minimum of 2,400 Class Members based on the following timeline:

7 a. A minimum of 1,200 Class Members within the first twelve (12) month period after
8 the Effective Date (for purposes of this provision any inmates treated under
9 Paragraph 36 shall be considered as part of the 1,200 inmates);

10 b. A minimum of an additional 600 Class Members within the second (12) month
11 period after the Effective Date; and

12 c. A minimum of an additional 600 Class Members within the third (12) month period
13 after the Effective Date.

14 38. After the above timeline is completed, thirty-six (36) months after the Effective Date,
15 Defendants agree to provide DAA treatment to Class Members within NDOC's custody at
16 a rate that, at a minimum, exceeds the HCV infection rate of new inmates who test HCV
17 positive, or who are confirmed to be HCV positive, during the intake process. For the
18 avoidance of ambiguity, if an additional 600 inmates tested positive for HCV during intake
19 in one calendar year, then Defendants agree to provide DAA treatment to at least 600 Class
20 Members in the same calendar year.

21 **D. Monitoring**

22 39. Class Counsel agree to be appointed as Monitors for the purposes of this Consent Decree.

23 40. For the duration of the Consent Decree, Defendants agree to timely provide Monitors and
24 the Court, in accordance with the Stipulated Protective Order and filed under seal or
25 redacted as necessary, with copies of Minutes of the HCV Committee within fourteen (14)
26 days of each meeting and comprehensive quarterly reports containing the following
27 categories of information:

28 a. The number of inmates tested/screened during the reporting period;

- b. The number of inmates who tested positive for HCV during the reporting period (including the date on which each inmate tested positive for HCV);
- c. The number of inmates who began receiving DAA Treatment (with an indication of which type of DAA Treatment was provided and the date on which DAA Treatment was initiated) during the reporting period;
- d. The number of inmates who concluded their course of DAA Treatment (with an indication of which type of DAA Treatment was provided and the date on which DAA Treatment was concluded) during the reporting period;
- e. The number of inmates who obtained SVR (cure) after completion of DAA treatment during the reporting period.
- f. The number of inmates who were tested after receiving DAA treatment but did not obtain SVR (cure) after completion of DAA treatment during the reporting period.
- g. The number of inmates for whom DAA Treatment was denied or delayed (with information and explanations for each denial/delay) during the reporting period.

15 41. Defendants agree to cooperate with Class Counsel to ensure that the above information is
16 provided in a reasonably usable and accessible format on a timely basis.

E. Attorney's Fees

18 42. Subject to separate approval by the Board of Examiners, the Parties agree Defendants will
19 provide an attorney's fees award of \$160,000 to Class Counsel ("Award"), which is a
20 discounted amount that Class Counsel has agreed to accept. The Consent Decree, without
21 the Award, can be separately approved by the IFC and/or Legislature even if the Board of
22 Examiners does not approve the Award. Should approval be provided to the Consent
23 Decree but not the Award, the Parties agree that Class Counsel may seek the non-
24 discounted amount of their attorney's fees as provided herein. The Award also includes
25 attorney's fees for ongoing monitoring to which Class Counsel may otherwise be entitled,
26 and, if approved, precludes a separate request by Class Counsel for the same. Upon
27 approval of the Award, apart from the Award and except as otherwise specified herein, the

1 Parties agree to bear their own attorney's fees arising from the litigation prior to the
2 Effective Date.

3 43. If the Award is not approved by the Board of Examiners, then the Parties agree this Consent
4 Decree does not resolve the issues of whether Class Counsel are entitled to attorney's fees
5 or the amount of those fees should they be awarded. The Parties agree to submit the matter
6 of whether attorney's fees are appropriate and the amount of those fees should they be
7 awarded, to Magistrate Judge Baldwin for a Report and Recommendation.

8 44. If the Award is not approved, the Parties agree that this Consent Decree shall not be deemed
9 to be an acknowledgement or admission that either Party is deemed to be a prevailing party
10 due to the Consent Decree. Plaintiffs assert they are the prevailing party in this action and
11 reserve the right to seek attorney's fees. Defendants do not agree and reserve the right to
12 contest that Plaintiffs are the prevailing parties in this action, that Class Counsel is entitled
13 to any attorney's fees, and the amount of attorney fees requested by Plaintiffs. Each Party
14 may rely on this Consent Decree and Appendix A in order to make their respective
15 arguments as to whether either party is a prevailing party and to argue the appropriateness
16 of attorney's fees being provided to either Party.

17 45. Any Party who is successful in any future motion or proceeding to enforce the terms of the
18 Consent Decree, will be entitled to seek and collect reasonable attorney's fees and costs of
19 suit incurred in prosecuting or defending such motions.

20 **F. Costs**

21 46. Defendants agree to reimburse the Federal Pro Bono Program and Class Counsel for costs
22 and expert witness fees in an amount not to exceed \$25,000. Class Counsel agrees to
23 provide NDOC's counsel with receipts, invoices, or other documentation needed to support
24 the reimbursement of the Federal Pro Bono Program and Class Counsel for these amounts
25 not to exceed \$25,000 in total. Apart from this reimbursement, and except as otherwise
26 specified herein, the Parties agree to bear their own costs arising from the litigation prior
27 to the Effective Date.

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G. Incentive Awards

47. The Parties agree that this Consent Decree shall not be deemed to be an acknowledgement or admission that any Class Representative is entitled to an Incentive Award due to the Consent Decree. Should any Class Representative with an existing case related to HCV seek an Incentive Award, NDOC agrees to not oppose such requests on the grounds that they are made in the separate action rather than the class or consolidated action, but reserves the right to challenge whether any Class Representative is entitled to Incentive Fees or monetary damages.

H. DISPUTE RESOLUTION

10 48. Any dispute shall be submitted to the Court for a hearing on the issues.

I. NOTICE TO THE CLASS

12 49. Prior to a fairness hearing, and early enough to provide practicable notice, the Parties will
13 provide Class Members with notice of the proposed Consent Decree and provide a
14 mechanism for ascertainable Class Representatives and Class Members to provide input
15 prior to or at the fairness hearing. The Parties also will provide ascertainable Class
16 Representatives and Class Members with an additional opt-out period prior to the fairness
17 hearing.

18 50. Defendants shall ensure that written notice to the Class Members is made known by posting
19 in conspicuous places throughout the NDOC institutions a notice to be jointly drafted by
20 the Parties' counsel following approval of this Consent Decree. The notice will be posted
21 within ten (10) days of it being agreed to by the Parties (and the Court should the Court
22 require its approval) and shall be posted for a minimum of thirty (30) days. Defendants
23 may also choose—but are not obligated to—place a copy of the notice in any medical file
24 of any identifiable HCV Inmate Patient.

J. ACCESS TO RELEVANT DOCUMENTS

26 51. The Parties agree that Class Counsel and the Court shall have access to all documents
27 necessary and relevant to the implementation of this Consent Decree subject to the terms

1 of the Stipulated Protective Order in this action and in a manner consistent with HIPAA's
2 protections regarding Protected Health Information.

3 **K. EFFECT OF SETTLEMENT/RESERVATION OF RIGHTS**

4 52. The Consent Decree shall be deemed to serve as a final judgment and resolution of claims
5 for prospective relief concerning Defendants' policies and practices for testing and
6 treatment of HCV, including MD 219 and the Consent Agreement. The Parties agree that
7 nothing in this Consent Decree precludes the Class Representatives or any other Class
8 Member from continuing their current individual lawsuits, or bringing future lawsuits,
9 seeking monetary damages. The Parties also agree that nothing in this Consent Decree
10 precludes any plaintiff from asserting other claims that do not pertain to the general
11 prospective relief issues addressed in the Consent Decree; further, a plaintiff may seek
12 injunctive relief for their individual claims based on the application of the revised policies
13 to that individual. The Consent Decree is not to be construed and shall never at any time
14 for any purpose be considered an admission of liability on the part of Defendants who
15 reserve all rights to defend themselves against any current or future claims, including for
16 monetary damages claims, without waiving any potential defenses, including sovereign
17 immunity, Eleventh Amendment Immunity, qualified immunity, discretionary acts
18 immunity, and any other common law, statutory defense, or affirmative defense that may
19 be applicable as a defense against any claim brought by a Class Member against the State,
20 NDOC, or any individual state employee in the future.

21 53. Notwithstanding the Parties' mutual promise to amicably resolve these issues, this Consent
22 Decree is contingent upon approval by the Board of Examiners, the IFC, and/or the
23 Legislature. While the Parties cannot bind these decisionmakers regarding whether to
24 approve or disapprove of this Consent Decree, the Governor's Office for the State of
25 Nevada has agreed to present and recommend the terms of this Consent Decree to the IFC
26 and/or Legislature for approval at the next possible opportunity.

27 54. This Consent Decree is contingent upon the approval of the Court as required under the
28 Federal Rules of Civil Procedure regarding class action settlements.

1 **VII. MISCELLANEOUS**

2 55. Mitigating Factors - This Consent Decree is based upon the unique circumstances and
3 mitigating factors relating to Class Action Lawsuit and shall not be considered in any
4 separate legal or administrative proceeding involving any other person, excluding the
5 Parties, for any purpose whatsoever.

6 56. Counterparts - This Consent Decree may be executed simultaneously in one or more
7 counterparts, each of which shall be deemed an original.

8 **VIII. RETENTION OF JURISDICTION**

9 57. The Court (Judge Du and Magistrate Judge Baldwin) shall retain jurisdiction to enforce the
10 terms of this Consent Decree.

11 **IX. MODIFICATION**

12 58. This Consent Decree shall not be modified in any way absent Court approval.

13 **X. SIGNATORIES**

14 59. Each undersigned representative certifies that he or she is fully authorized to enter into the
15 terms and conditions of this Consent Decree and to execute and legally bind the Party he
16 or she represents to this document.

17 **XI. FINAL JUDGMENT**

18 60. Upon approval and entry of this Consent Decree by the Court, this Consent Decree shall
19 constitute a final judgment of the Court in Case No. 3:19-cv-00577-MMD-CLB.

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1 61. This Consent Decree will terminate four years from the Effective Date, but the Court may
2 extend this Consent Decree and/or any of its provisions for good cause in the event that
3 Defendants have failed to substantially comply.

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5 Dated: _____

6 McDONALD CARANO LLP

7

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40 SO ORDERED THIS _____ DAY OF _____ 2020

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APPENDIX A

Medical Directive 219

APPENDIX A

EFFECTIVE DATE: 07/2020

MEDICAL DIRECTIVE

NUMBER: 219

TITLE: HEPATITIS C, TREATMENT OF

PURPOSE:

These guidelines represent the treatment of Hepatitis C in the Nevada Department of Corrections. These guidelines assist medical practitioners in evaluating patients. However, nothing in these guidelines take precedence over a case-by-case determination of the medical needs of the patient. The goal of treatment of Hepatitis C-infected persons is to reduce Hepatitis-C transmission and associated morbidity and mortality by the timely achievement of a virologic cure as evidenced by a sustained virologic response.

AUTHORITY:

AR 621, NRS 209.381, NAC 441A, NAC 441A.570

RESPONSIBILITY:

Medical Division staff has the responsibility to have knowledge of and comply with this procedure.

DEFINITIONS:

HEPATITIS C - A blood borne pathogen transmitted primarily by way of percutaneous exposure to blood.

HCV – Chronic Hepatitis C as diagnosed by a qualified medical practitioner

DAA – Direct Acting Antiviral treatment in the form of an FDA-approved treatment for HCV, which may include, without limitation, Epclusa (sofosbuvir/velpatasvir) or Mavyret (glecaprevir/pibrentasvir)

PRACTITIONER - Physician, Physician Assistant, or Advanced Practice Registered Nurse

PROCEDURES:

219.01 TESTING FOR HEPATITIS C AT INTAKE

- 1 Unless an inmate refuses or chooses to opt out of Hepatitis C testing, all inmates will be tested for Hepatitis C during the Intake process and all inmates who have not previously been tested will be tested. Inmates who refuse Hepatitis testing must sign a DOC 2523 at the point of refusal. If at any time in the future the State of Nevada requires Hepatitis C to be a mandatory test (e.g., TB), then inmates will not be provided the opportunity to opt

out of testing, and any inmate who previously opted out will be required to cooperate in testing.

2 The following are CDC identified risk factors for a possible Hepatitis C infection to guide whether an inmate should be re-tested for Hepatitis C:

- a. Ever injected illegal drugs or shared equipment (including intranasal use of illicit drugs)
- b. Received tattoos or body piercings while in jail or prison, or from any unregulated source
- c. HIV or chronic Hepatitis B virus (HBV) infection
- d. Received a blood transfusion or an organ transplant before 1992, received clotting factor transfusion prior to 1987, or received blood from a donor who later tested positive for HCV infection
- e. History of percutaneous exposure to blood
- f. Ever received hemodialysis
- g. Born to a mother who had HCV infection at the time of delivery
- h. Born between 1945 and 1965

219.02 EVALUATION FOR HEPATITIS C TREATMENT

Institutional procedure:

- a. All inmates who have tested positive for HCV are candidates for treatment with DAAs.
- b. All inmates with HCV will receive DAA treatment unless there are medical reasons indicating treatment with DAAs is not medically appropriate or necessary. Inmates with HCV will be prioritized in accordance with the medical priorities outlined in MD 219.04.
- c. All candidates must be enrolled in the Infectious Disease Chronic Clinic for Hepatitis C using DOC 2689 Chronic Disease Clinic Enrollment Form and the enrollment entered into NOTIS.
- d. NDOC will maintain an HCV Committee which shall consist of the Medical Director or designee and at least two (2) institutional practitioners. The HCV Committee shall meet at least once per month.
- e. The HCV Committee shall be presented with a DOC 2698 Hepatitis C Patient Data Form with all backup documentation for each case to be discussed during the

meeting.

- f. In accordance with this Medical Directive, the Committee will discuss medical cases of HCV inmate patients related to prioritization, classification, and evaluation and shall make referrals to an outside provider for DAA treatment.
- g. Medical staff will initiate Hepatitis C Treatment protocol orders per DOC 2518 Physician Orders – Hep C.
- h. Inmate patients will be scheduled with a provider to review and sign DOC 2730 Hepatitis C Treatment Consent-Agreement.
 - i. The inmate patient will be informed that noncompliance with DOC 2730 Hepatitis C Treatment Consent-Agreement will result in the inmate patient being responsible for all future costs of HCV treatment if they become re-infected after successfully completing the DAA Treatment and obtaining SVR.
 - ii. The inmate patient will be informed that noncompliance with DOC 2730 Hepatitis C Treatment Consent-Agreement may result in the delay of HCV treatment for medical reasons based on the Practitioner's medical opinion. Any possible delay in treatment will not occur if the delay in treatment would cause the inmate patient's medical condition to worsen or would result in patients in a lower priority level (as defined in MD 219.04) being sequenced for treatment before the inmate patient per MD 219.04. Instead, any delay may result in the inmate patient being placed after similarly situated medical patients but still within the same priority level for treatment.
 - iii. The inmate patient's prior six-month disciplinary history will be reviewed for evidence of high-risk behaviors for HCV infection. The inmate patient will be provided with necessary resources to educate the patient as to the dangers of high-risk behaviors (fresh tattoos, drug use, possession of controlled substances or alcohol, assaultive behavior, and any sexual activity) and provided with resources to overcome any potential addiction. The disciplinary history review will not be used to deny or delay DAA Treatment unless a Practitioner identifies medical reasons indicating that treatment with DAAs is not medically appropriate or necessary at the time.
 - i. Any inmates with HCV who have not been treated with DAAs will be evaluated every six months (including obtaining a new APRI score), per Medical Directive 447, Attachment A.

219.03 TREATMENT OF HEPATITIS C

- a. All inmates who have tested positive for HCV are candidates for treatment with DAAs so long as they have sufficient time remaining on their sentence. Sufficient

time is defined for the purposes of this section as 120 days remaining on the sentence from the beginning date of the DAA Treatment.

- b. Treatment will be conducted in conformity with MD 219.04 and MD 219.05.

219.04 PRIORITY CRITERIA FOR HEPATITIS C TREATMENT

Treating patients during incarceration saves lives and reduces the transmission of HCV among people with high-risk behaviors. Although almost all patients with HCV will benefit from treatment, certain patients are at higher-risk for disease progression. Treatment of inmate patients shall be sequenced based on the below priority levels for more urgent administration of treatment. The following criteria have been established to ensure those with the highest need and greatest likelihood of achieving a sustained viral response (cure) are identified and treated first.

Priority Level	Criteria
Priority Level 1 Highest Priority for treatment	<ul style="list-style-type: none"> • Advanced hepatic fibrosis: APRI >2.0, Metavir or Batts/Ludwig stage 3 or 4 on liver biopsy, cirrhosis (FibroSure is not required to be (but may be) drawn if the APRI score is 2.0 or greater). • APRI score is between 0.7 and 1.9 AND FibroSure Score of F3 or F4 • Liver transplant recipients • Hepatocellular carcinoma (HCC) • Comorbid conditions associated with HCV, e.g. cryoglobulinemia with renal disease or vasculitis and certain types of lymphomas or hematologic malignancies or porphyria cutanea tarda • Immunosuppressant medication • Continuity of care: when started on treatment prior to incarceration
Priority Level 2 Intermediate Priority for treatment	<ul style="list-style-type: none"> • Evidence for progressive fibrosis: APRI score ≥ 0.70, stage 2 fibrosis on liver biopsy • APRI score is less than 0.7, but constitutional signs and symptoms (i.e. bleeding or bruising easily, ascites and/or jaundice) are present (FibroSure is not required to be (but may be) drawn if the APRI score is 0.69 or less). If an inmate patient's APRI score is less than 0.7, but constitutional signs and symptoms (i.e. bleeding or bruising easily, ascites and/or jaundice) are present, the inmate patient may be evaluated further) • Comorbid Medical conditions such as coinfection with HBV or HIV, comorbid liver diseases (autoimmune hepatitis, hemochromatosis, steatohepatitis) • Diabetes mellitus • Chronic kidney disease (CKD); GFR < 59 mL/min
Priority Level 3 All other candidates	<ul style="list-style-type: none"> • Stage 0 to stage 1 fibrosis on liver biopsy • APRI <0.70 with no constitutional signs and symptoms (i.e. bleeding or bruising easily, ascites and/or jaundice) present (FibroSure is not required to be (but may be drawn if the APRI score is 0.69 or less)) • All other cases of HCV infection meeting the eligibility criteria for treatment as noted below under Other Criteria for Treatment

***EXCEPTIONS** to the above criteria for PRIORITY LEVEL 1-3 will be made on an individual basis and will be determined primarily by a compelling or urgent need for treatment, such as evidence for rapid progression of fibrosis, or deteriorating health status from other comorbidities.

219.05 POSSIBLE CONTRAINDICATIONS FOR TREATMENT:

Below are issues that could possibly lead to a contraindication for DAA Treatment. Therefore, should any of these conditions be present, medical evaluations may be necessary as per MD 219.03 and 219.04. The medical evaluations will be performed by Practitioner examining the inmate patient as part of the inmate patient's enrollment in the Chronic Care Clinic. These contraindications include:

- a. Insufficient time remaining on the sentence to complete DAA treatment. Insufficient time is defined as fewer than 120 days remaining on the sentence in NDOC.
- b. Contraindications to any component of the treatment regimens (including other medications that may be necessary in conjunction with DAA Treatment).
- c. Failure to complete the pretreatment evaluation process, or an unwillingness to commit or consent to HCV treatment.
- d. Severe decompensated liver disease.
- e. Any other end stage disease process that would cause a contraindication to the DAA Treatment.
- f. Current pregnancy.
- g. Life expectancy of less than twelve (12) months.
- h. Uncontrolled seizures.
- i. Failure to maintain compliance with signed Hepatitis C Treatment Consent/Agreement (DOC 2730), which may result in a medical need to delay treatment on a case-by-case basis as determined by the medical provider. Any possible delay in treatment will not occur if the delay in treatment would cause the medical condition to worsen or would result in patients with a lower priority level (as defined in MD 219.04) being sequenced for treatment before the patient in question per MD 219.04. Instead, any delay may result in the patient in question being placed after similarly situated medical patients but still within the same priority level for treatment.
- j. Boarders from other political subdivisions of the State of Nevada will be considered for treatment based on their priority level, but after all non-boarders within the same priority level as referenced in 219.04 receive treatment.

REFERENCES:

Federal Bureau of Prisons Clinical Practice Guidelines, “Evaluation and Management of Chronic Hepatitis C Virus (HCV) Infection”, August 2018.

Michael Minev, M.D., Medical Director

Date

CONFIDENTIAL

Yes

X
No

THIS PROCEDURE SUPERSEDES ALL PRIOR WRITTEN PROCEDURES ON THIS SPECIFIC SUBJECT.

APPENDIX B

HCV Consent Agreement

APPENDIX B

Treatment of Hepatitis C is available to all patients but is prioritized to patients who understand the commitment to therapy, will tolerate and comply with the course of treatment, and agree to avoid all activities that may worsen their liver disease or infect themselves or others with the Hepatitis C virus or other bloodborne pathogens. Every patient must complete this consent/agreement before initiation of therapy.

(Please initial each statement and sign below to indicate your understanding of all parts of this document)

I understand that there is a possibility that the therapy may be of no benefit to me and that it may not get rid of my Hepatitis C infection.

I have been informed that side effects of treatment of Hepatitis C may include fatigue, body aches, and other serious side effects that may continue through my treatment with the medication.

I understand that I may be tested for HIV before beginning treatment as the presence of the HIV virus could seriously affect my Hepatitis C infection and its treatment.

I understand that the treatment with medication typically lasts between 8-12 weeks, but may continue for up to 36 weeks and that frequent blood testing may be needed to check for side effects or other problems. To the extent your treatment is not completed before the expiration of your sentence (which will only occur in the rare instance that you begin treatment within 120 days of your expiration date), you will be responsible for ensuring that the treatment is completed upon release from NDOC custody because any interruption in the treatment could result in the treatment being unsuccessful.

I understand that treatment for Hepatitis C may, in certain patients, cause mental health side effects, especially depression.

I understand that I should avoid becoming pregnant while receiving treatment, and that I should use two forms of birth control during heterosexual activity while taking medication, and for six months after, in an effort to avoid pregnancy.

I understand that my failure to comply with the medication, blood testing, or regular appointments may result in a medical need for my provider stopping the therapy.

I understand that alcohol injures the liver and that drinking alcohol is forbidden.

I understand that I must abstain from any activity that may transmit the Hepatitis C virus or other bloodborne pathogens. This includes tattooing, sexual activity in NDOC custody, IV drug use, and intranasal drug use.

If I become reinfected after the completion of the course of treatment due to my decision to engage in tattooing, sexual activity, IV drug use, intranasal drug use, or other prohibited behaviors, I may be charged for the cost of future treatment.

I understand that I may be required to undergo random blood or urine testing for illegal substances.

I understand that failure to comply with this agreement, including but not limited to testing positive for illegal substances or engaging in other prohibited behaviors, could increase the likelihood of re-infection or could reduce the likelihood of successful treatment. I understand that should I engage in any of these prohibited activities my medical provider may (but is not required to) delay treatment if that provider believes the medical benefits of treating other medical conditions (that would lead me to becoming more susceptible to re-infection or other health consequences) prior to initiating treatment outweigh the risks of delaying treatment. However, I also understand that any possible delay in treatment will not occur if the delay in treatment would cause my medical condition to worsen or would result in patients in a lower priority level (as defined in MD 219.04) being sequenced for treatment before me per MD 219.04. Instead, any delay may result in me being placed after similarly situated medical patients but still within the same priority level for treatment.

My initials above and my signature below signify my understanding of, and agreement to comply with, the requirements.

Inmate/patient Name: _____

Inmate/patient Signature: _____ Date: ____ / ____

Clinician Name: _____

Clinician Signature: _____ Date: ____ / ____

NEVADA DEPARTMENT OF CORRECTIONS

NAME:

Last

First

ID: _____

**HEPATITIS C TREATMENT
CONSENT/AGREEMENT**

DOC 2730 (08/19)
